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Accuracy of intraocular pressure measurements made over soft contact lenses using Tonopen XL and Pulsair 2000

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Abstract

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ACCURACY OF INTRAOCULAR PRESSURE MEASUREMENTS MADE OVER SOFT CONTACT LENSES USING TONOPEN XL AND PULSAIR 2000

BY

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ABSTRACT

The purpose of this investigation was to determine if intraocular pressure measurements made over soft contact lenses are affected by the refractive power of the contact lens and the type of tonometer used. Forty subjects ranging in age from 19 to 45 years, free from corneal abnormalities and glaucoma, participated in this study. Four minus power soft contact lenses, each having the same diameter, base curve, and central thickness, but differing in power (-1.50D to -6.00D) were chosen. Intraocular pressures were measured over these lenses using two different tonometers, the Tonopen XL and Pulsair 2000. Results showed that intraocular pressure was not affected either by the power of the lens or the type of tonometer used. The differences in mean intraocular pressure with and without lenses were found to be statistically significant. This variability was however clinically acceptable, as the differences were within 1mm of each other. In conclusion, intraocular pressure measurements taken over standard minus lenses with the Tonopen XL and Pulsair 2000 are reliable and acceptable.

KEY WORDS

Tonometry, applanation tonometer, air-puff tonometer, intraocular pressure, Tonopen XL , Pulsair 2000, soft contact lenses.

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I would like to thank Ciba Vision for donating the soft contact lenses used in this study, and Bio-Rad Ophthalmics for loaning the Tonopen XL. I would like to express my gratitude to my advisors for all their help and guidance. A special thanks to all the subjects who readily agreed to participate in this study.

Dedication....

To my loving family and friends. Thank you for helping me get there, and for your love, affection, and support. And above all, for being there whenever I needed you.

CONTENTS

INTRODUCTION:

Tonometry, which is the measurement of intraocular pressure (IOP), is performed routinely in optometric practices and has become part of a regular ocular examination. Along with visual field and optic nerve head examination, it is used to diagnose glaucoma and to monitor the patient's response to therapy.

All clinical tonometers measure intraocular pressure by relating a deformation of the globe to the force responsible for the deformation. Depending on the technique used to deform the globe, tonometers are broadly classified into two groups: applanation and indentation.[1] Since its advent in 1954, the most frequently used tonometer in clinical practice is the Goldmann applanation tonometer. It is a variable force applanation tonometer as it measures the force required to applanate or flatten a standard area of the corneal surface. For eyes with normal corneas, the Goldmann tonometer has been accepted as the standard against which all other tonometers have been compared, because of its accuracy and reliability.

DISADVANTAGES OF THE GOLDMANN APPLANATION TONOMETER:

The Goldmann tonometer has some performance limitations. It requires the use of pharmaceutical agents such as local anesthetics and fluorescein. Studies show that the Goldmann tonometer gives inaccurate readings in patients with gross corneal edema or irregular curvature.[1] Prolonged contact of the biprism with the cornea can lead to corneal injury, as manifested by staining.[2] There is a risk of microbial contamination of the biprism and therefore it requires disinfection after each use. It is subject to the errors of technique-a wider circular meniscus or unequal vertical alignment of the semicircles may give falsely high pressure results.[1]

In addition to these problems, use of the Goldmann tonometer requires the removal of contact lenses prior to measurement of IOP. The instillation of fluorescein and local

anesthetic prevents immediate replacement of the contact lens after the IOP has been measured. This is because the fluorescein solution that remains on the surface of the eye may cause permanent staining of the soft contact lens.[3] In clinical practice, lens staining and risk of lens insertion when the cornea has been desensitized, is reduced by complete eye irrigation, and waiting one hour before replacing the lens.[4] During this period, a patient without spectacle correction may be inconvenienced by blurred vision.

ADVANTAGES OF MEASURING INTRAOCULAR PRESSURE OVER SOFT CONTACT LENSES:

There are many occasions when measurement of intraocular pressure over soft contact lenses using a tonometer other than a Goldmann, becomes either necessary or advantageous. There are 20-26 million people in the U.S. wearing soft contact lenses and the ability to measure IOP without removing these lenses would be more time effective in clinical practice.

The insidious nature of glaucoma makes its detection extremely crucial, because early diagnosis can greatly reduce the risk of optic nerve damage and blindness. An optimal method of screening should include optic disc and visual field examinations. These methods are not commonplace in screening protocols, however, as they are expensive, time consuming and their interpretation requires special skills. Thus IOP remains the one sign that can be used easily for glaucoma screening. However, screenings are generally characterized by two commonly seen features: poor hygienic surroundings which discourage the removal and insertion of contact lens; and limited access to instruments of choice such as a slit lamp and Goldmann applanation tonometer. In such situations, measurements of IOP over a patient's soft contact lens can be greatly beneficial.

Corneal pathology such as recurrent corneal erosions[5] or dry eye may contraindicate the use of local anesthetics, due to their adverse side effects.[6] Such conditions usually require therapeutic soft contact lenses to protect the cornea while it re-epithelializes.

Post-operative keratoplasty patients require careful monitoring of IOP because untreated pressure elevation can lead to optic nerve damage, endothelial cell loss and failure of the graft[7]. In such conditions, measurement of IOP over therapeutic (bandage) contact lenses using non-contact tonometers can be extremely advantageous, because pressures can be obtained without disturbing the corneal integrity.

LITERATURE REVIEW:

If IOPs were to be measured over soft contact lenses what are the parameters of the contact lens that would affect the accuracy of measurements? To study this, air-puff tonometry was performed over soft contact lenses. In a study[8], the American Optical Non-Contact Tonometer was used to measure the IOP over plus and minus power lenses. It was found that lenses with central thickness greater than 0.15 mm would produce an apparent increase in IOP. This was explained by the fact that the Non-Contact Tonometer delivers an air-pulse with a force that would cause an applanation of the contact lens-cornea combination. The presence of a contact lens greater than 0.15 mm in central thickness could lead to higher IOP readings because the air-pulse must compress and deform the contact lens as well as the cornea. However, an earlier study[9] had concluded that IOPs were clinically valid with lenses having central thickness upto 0.45 mm. While these studies support the central thickness effect, a more recent investigation concluded otherwise. This study,[10] used four brands of therapeutic contact lenses having different central thickness (0.035 mm, 0.18 mm, 0.24 mm and 0.30 mm) and measured IOP using both the Tonopen and Pneumatonometer. Using thickness and water content as independent variables, they found that lens thickness provided only a minor influence (0.09%) on IOP. They concluded that IOPs assessed over contact lenses were comparable to measurement with and without them.

The American Optical Non-Contact Tonometer II was used in a study,[9] to measure IOP over minus and plus lenses. It was found that the power of the contact lens had a significant effect on the measured IOP and that as the power of the lens was changed

from minus to plus, the difference in IOP with and without soft contact lenses became significantly larger. This was also concluded in another study,[11] where IOP measurements made over high plus and minus contact lenses with a Tonopen were found to be significantly biased, but were not so when measured over a plano therapeutic contact lens. In contrast, other studies[12,13] have concluded differently. These studies used the Tonopen to measure IOP of live human eyes which were free of glaucoma or other abnormalities. One study,[12] used Ciba Vision's NueVue (Vifilcon 55%) with refractive powers ranging from +1.75 to -7.00 diopters, and found that the mean difference with and without lenses was only 1.34 mm Hg. The other study,[13] used Cooper Vision Plano Permalens (Perfilcon A 71%) and found the mean differences between readings before lens insertion and readings obtained with the lenses in place was 0.27 mm Hg (ranges from -0.3 to +1.5 mm Hg).

OBJECTIVES OF THIS STUDY:

There seems to be a considerable difference in opinion as to whether valid IOP readings can be obtained over soft contact lenses. This study addresses two questions. One, is the IOP which is measured over soft contact lenses, affected by the refractive power of the lens? Two, is the IOP which is measured over soft contact lenses affected by the type of tonometer used? To answer the first question, four contact lenses which differed in power but which were of the same material, water content, base curve, diameter and central thickness were chosen. Any differences in IOP measurements could therefore be attributed to only one parameter-i.e. power. The refractive power of the lenses varied from -1.50 to -6.00 diopters. This range was chosen for two reasons. First, nearly 80% of the 21 million soft contact lens wearers in the United States require minus lenses,[a] therefore these lenses would be more representative of what one would encounter most commonly in an optometric practice. Secondly, most lenses dispensed in this range usually have a central thickness around 0.10 mm,[a] which is within the limit (0.15mm) the McMonnies study[8] recommended. In this study, all four lenses had the same central thickness of 0.10 mm (as specified by the manufacturer).

To study the extent to which tonometers affect the accuracy of IOP readings, two tonometers (Tonopen XL and Pulsair 2000) that use different techniques to deform the cornea were chosen. Four studies[10,11,12,13] have been done to evaluate measurement of IOP over soft contact lenses using the Tonopen. Of these, two studies[10,11] used cadaver eyes and one study restricted the lens choice to plano bandage contact lenses.[13] So far only one study,[12] has been done that has used live human eyes and disposable soft contact lenses. No study has been done to measure IOP over soft contact lenses using the Pulsair 2000, nor has any study been done comparing the Tonopen XL to the Pulsair 2000.

TONOPEN XL AND PULSAIR 2000:

Some of the disadvantages of the Goldmann applanation tonometer (as discussed above) have been overcome with the use of newer instruments. Two tonometers, the Tonopen XL (Bio-Rad Ophthalmic Division) and Pulsair 2000 (Keeler) were used in this study. Like the Goldmann, they are based on the Imbert-Fick law which states that the force required to applanate a given corneal area is directly proportional to the IOP.[1] However, the two instruments use different techniques to deform the cornea. The Tonopen XL mechanically applanates the cornea while the Pulsair 2000 uses an air-puff.

The accuracy and reliability of the two instruments have been well studied. In a clinical evaluation,[14] the Tonopen was compared to Goldmann and it was found that for IOP ranges between 6-24 mm Hg, the Tonopen differed from the Goldmann by an average of 1.7 mm Hg (which was found to be statistically significant). In the IOP range above 24 mm Hg, no statistically significant differences were found in the pressures measured with the two instruments. The study concluded that the measurements made with Tonopen were sufficiently close to those made with Goldmann to be considered clinically accurate. In contrast, other studies comparing the Tonopen to Goldmann concluded that the Tonopen underestimated IOP in ranges over 30 mm Hg; therefore the validity of the Tonopen has been questioned.[15,16]

Studies have shown that the Tonopen is a good screening instrument. It has been compared with the Goldmann tonometer in subjects with glaucoma and ocular hypertension,[15] and was found to be adequate for screening programs in which an IOP of 21 mm Hg or above is considered abnormal. Another comparative study found the Tonopen to have a sensitivity (false positive) of 91% and specificity (false negative) of 95% for detecting IOP over 21 mm Hg.[17] Mackay-Marg tonometers can measure IOP with corneas that are irregular due to scarring, edema, or surgery with greater accuracy than other applanation tonometers.[1,18] The Tonopen (which operates on the Mackay-Marg principle) has been extensively studied for accuracy in measuring IOP in post-operative patients. It has been found to be accurate in patients after keratoplasty, epikeratophakia,[7] and vitrectomy.[19]

The Pulsair 2000 is the much improved version of the original Keeler Pulsair.[20] A study comparing different air-puff tonometers with Goldmann found that 91% of the eyes measured with the Pulsair 2000 had pressures within 3 mm Hg of the corresponding Goldmann IOPs, compared to 64% with the original Keeler, 69% with CT-10 (Topcon), 72% with XPERT (Reichert), and 80% with NCT II (Reichert), respectively.[21] The Pulsair 2000 was found to be 93% sensitive and 94% specific for determining IOP over 21 mm Hg.[17]

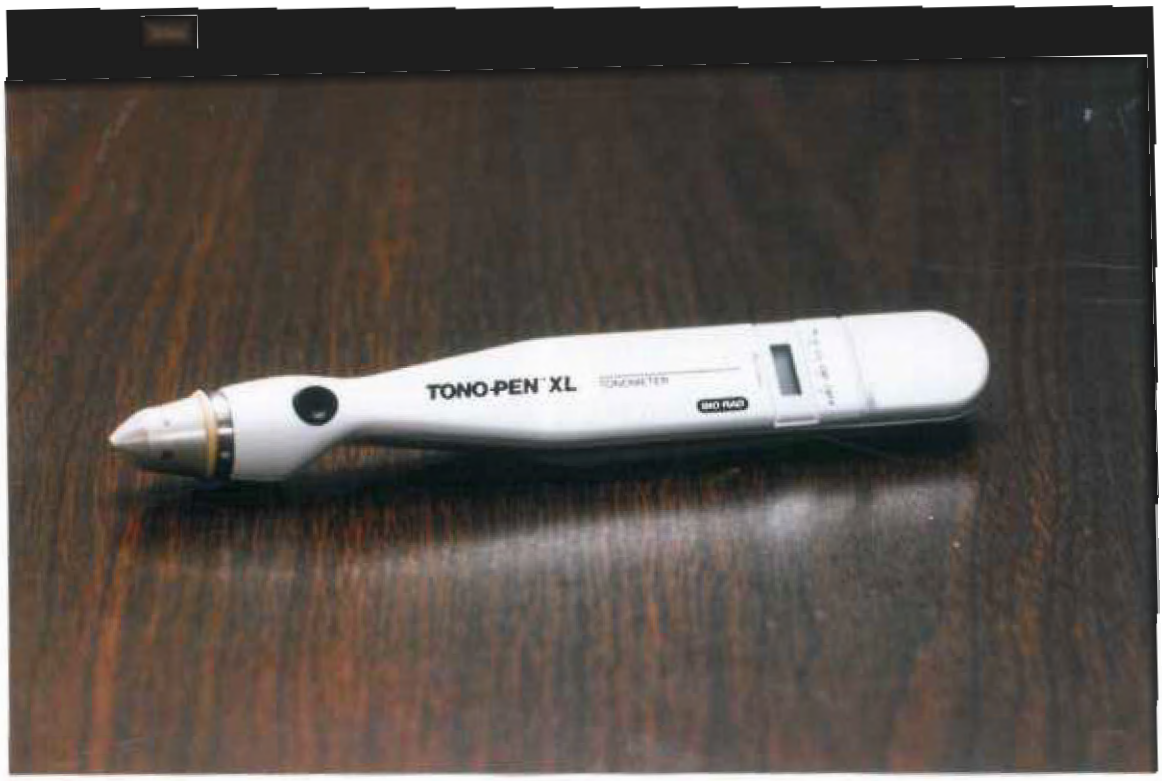
The Tonopen XL and Pulsair 2000 share some common features. They are both handheld, portable, easy to use and calibrate, and are claimed to be good screening devices with an average error less than 3 mm for both instruments. The sensitivity (false positive) and specificity (false negative) for detecting pressures above 21mm of Hg is over 90% for both instruments.[17] IOP measurements are made without corneal contact with the Pulsair 2000, thereby reducing the risk of corneal trauma. The disposable latex membrane used in the Tonopen XL reduces spread of infection and eliminates the need for probe disinfection. Both tonometers require minimum patient cooperation, and being portable, can be used for young and supine patients. They also

rely minimally on an operator's expertise or technique because the readings are only obtained when the instruments are correctly aligned. The endpoints for both instruments are digital readouts rather than subjective estimation of semi-circle alignment, as with the Goldmann tonometer.

When the Pulsair 2000 and Tonopen XL are compared, the Tonopen is more compact, portable, and can be used on abnormal corneas making it a better choice for screening. However, the disadvantages are that it underestimates the IOP at higher ranges and requires a constant supply of latex covers and batteries. The advantages of Pulsair are that it is considerably quieter and less startling to patients than other non-contact tonometers, and has been found to be especially useful with pediatric patients. A recent study[22] found that the Pulsair was a good choice for screening and follow-up in children. It reported that in a study group of 42 children, the youngest subject on whom the Pulsair measurements could be done was 18 months, as compared to 6 years for the Goldmann. Although the most attractive feature of an air-puff tonometer is its non-contact operation, a recent study[23] which used high speed photography showed microaerosal formation of the tear film, thus introducing the possibility of spreading of adenovirus or other contaminants to the examiner.

PULSAIR 2000 (KEELER)

TONOPEN XL (BIO-RAD OPHTHALMICS)



MATERIALS AND METHODS:

INSTRUMENTS:

The Tonopen XL is a hand-held, battery operated electronic tonometer which is 18 cm in length, 2 cm in width, weighs about 60g and operates on the Mackay-Marg principle.[17] It has a 1.02 mm diameter central plunger surrounded by a foot plate. The stainless steel probe contains a solid strain gauge which senses the force required to overcome the corneal rigidity and bend the cornea. This force is then converted to an electric signal using a single chip microprocessor, and, is displayed as the IOP. An audible beep indicates the readiness of the Tonopen to make a measurement. A click is heard each time a reading is obtained and when a final beep sounds, the display shows the averaged pressure measurements. When 4 valid readings are obtained, the mean IOP and a coefficient of variance ranging from 5 to 20 % is displayed. The display of results is maintained for 20 seconds. A disposable latex membrane is used over the tip to protect the probe, and to prevent spread of infection such as epidemic keratoconjunctivitis,[1] and more serious diseases such as hepatitis and acquired immune deficiency syndrome.

The Pulsair 2000, which is an updated version of the original Keeler Pulsair, is a non contact tonometer which applanates the cornea using a pulse of air.[21] It weighs 22 lbs and has a handpiece on a 2m cord. A pulse of air is released automatically when the Pulsair eyepiece is held at an optimal distance and orientation to the patient's cornea.[24] The operator achieves this alignment by focusing a red light target image onto the corneal surface. When the Pulsair is aligned perpendicularly and is at the correct distance from the cornea, it fires its stored air bolus. Corneal deflection is detected electronically as a red light reflects onto the three photo detectors. When a corneal area of 3.00 mm diameter is deflected, an internal transducer measures the air-pulse force.

This is then converted to a pressure reading which appears on a digital display within milliseconds. To minimize the influence of momentary fluctuations in IOP, the manufacturer suggests an average of 4 readings be taken from each eye. Studies conducted previously show that multiple readings do not affect IOP readings.[25] The Pulsair 2000[21] has a revised computer algorithm designed to give pressure readings that correspond more closely to Goldmann values than the original model. Another advantage of the Pulsair 2000 is that it has replaceable integrated circuits that can be updated to incorporate new algorithms as they are developed.

CONTACT LENS SPECIFICATIONS:

The contact lenses used in the study were Ciba Vision Corporation's Focus programmed replacement lenses (see Table 1). All four lenses were made of the same material, water content, base curve, central thickness and diameter; and differed only in refractive power.

TABLE 1: SPECIFICATIONS OF THE CONTACT LENSES USED IN THE EXPERIMENT.

Lens name / manufacturer	**Focus / Ciba**
Polymer (% water content)	**Vifilcon (45%)**
Base curve	**8.6 mm**
Diameter	**14 mm**
Thickness	**0.10 mm**
Power	**-1.50D, -3.00D, -4.50D, -6.00 D**

SUBJECTS:

Forty adult subjects without corneal abnormalities or glaucoma ranging in age from 19 to 45 years were recruited. An informed consent was obtained from each subject. All the subjects were tested at the same location (Pacific University, College of Optometry). The subjects were compensated for their participation in the study with a free vision exam at Pacific University's Vision Clinic. The total time spent with each subject was about 30-40 minutes.

METHODOLOGY:

The IOP was first measured without lenses by using the Tonopen XL and Pulsair 2000. (pre-insertion IOP). A random number table was used to select which instrument would be used first and the measurement was always carried out on the right eye first. A pair of lenses having the same power were chosen by using a random number table and fitted in both eyes. IOPs were then measured with the lenses in place. The lenses were next removed and another set of readings were taken (post-removal IOP). An interval of 5 minutes was always maintained between each set of readings. This is the time interval which has been suggested to minimize the effect of contact lens removal and manipulation.[26] All the readings were taken by the same trained investigator. Both instruments were calibrated each day before use, as per the manufacturer's instructions. The latex membrane (Ocu-Film) covering the tip of the Tonopen was changed before use on each subject. Only readouts showing high reliability (less than 5% variability) were recorded. An average of four readings were taken with each instrument to compensate for the fluctuations due to ocular pulsations.

STATISTICAL ANALYSIS:

Data were recorded and analysed using StatView 512, a statistical package for the Macintosh. A three factor analysis of variance (ANOVA) for repeated measures using a 95% level of confidence was computed. The power of the contact lens and type of

instrument were designated as the independent variables and the corresponding IOP values were the dependent variables.

RESULTS:

Of the forty subjects recruited, one was excluded from the study because he presented with allergic conjunctivitis. The statistical analysis required balanced data, therefore the overall mean IOP of all experimental conditions was used to complete the data.

Table 2 is a summary of the three factor repeated measures ANOVA and shows that the IOP was not affected by the type of tonometer used (A) or the lens powers (B). The interaction effect between the power of the lens and the instrument (AB), was also found to be insignificant. The main effect for factor C (repeated measure) was found to be statistically significant. This indicates that there was a difference in IOP means in the three experimental conditions (with and without lens). Inspection of the data however, shows that the means for the different conditions are within 1mm of each other. Even though this finding was of statistical significance, it was not of clinical significance.

Table 3 shows the means of IOP with and without lenses (pre-insertion and post removal) using Tonopen XL and Pulsair 2000. The mean IOPs measured with -3.00 D lens in place were slightly lower than the means recorded with the other lenses. This trend was seen with both the Tonopen XL and Pulsair 2000.

TABLE: 2 THREE FACTOR REPEATED MEASURES ANALYSIS OF VARIANCE ON IOP READING:

Source	Df	Sum of squares	Mean square	F-Test	P value
Tonometer (A)	1	4.82	4.82	0.31	0.58
Lens (B)	3	115.11	38.37	2.46	0.07
AB	3	4.69	1.56	0.10	0.96
Subjects with groups	72	1123.21	15.6		
Repeated measure (C)	2	20.1	10.03	6.16	0.002*
AC	2	0.008	0.004	0.003	0.99
BC	6	5.27	0.88	0.54	0.77
ABC	6	13.40	2.23	1.37	0.23
C x subjects w. groups	144	234.41	1.62		

TABLE 3: MEANS OF IOP USING TONOPEN XL AND PULSAIR 2000 TO MEASURE IOP OVER FOUR DIFFERENT LENS POWERS:

LENS CONDITION	COUNT	TONOPEN XL MEAN IOP mm Hg	PULSAIR 2000 MEAN IOP mm Hg
PRE INSERTION IOP	10	14.1	13.8
IOP WITH -1.50 D IN PLACE	10	13.6	14
POST REMOVAL IOP	10	14	13
PRE INSERTION IOP	10	12.4	13.1
IOP WITH -3.00 D IN PLACE	10	12.8	12
POST REMOVAL IOP	10	12.2	12.2
PRE INSERTION IOP	10	14.79	13.49
IOP WITH -4.50 D IN PLACE	10	13.33	12.73
POST REMOVAL IOP	10	13.33	13.03
PRE INSERTION IOP	10	14.9	14.7
IOP WITH -6.00D IN PLACE	10	14.2	14.1
POST REMOVAL	10	14.1	14.2

Figure 1 is a graphical representation of the AB incidence table which compares the effects of lens power and the type of tonometer on IOP measurements.

FIGURE 1: THE EFFECTS OF POWER OF CONTACT LENS AND TYPE OF TONOMETER USED ON THE INTRAOCULAR PRESSURE MEASUREMENTS

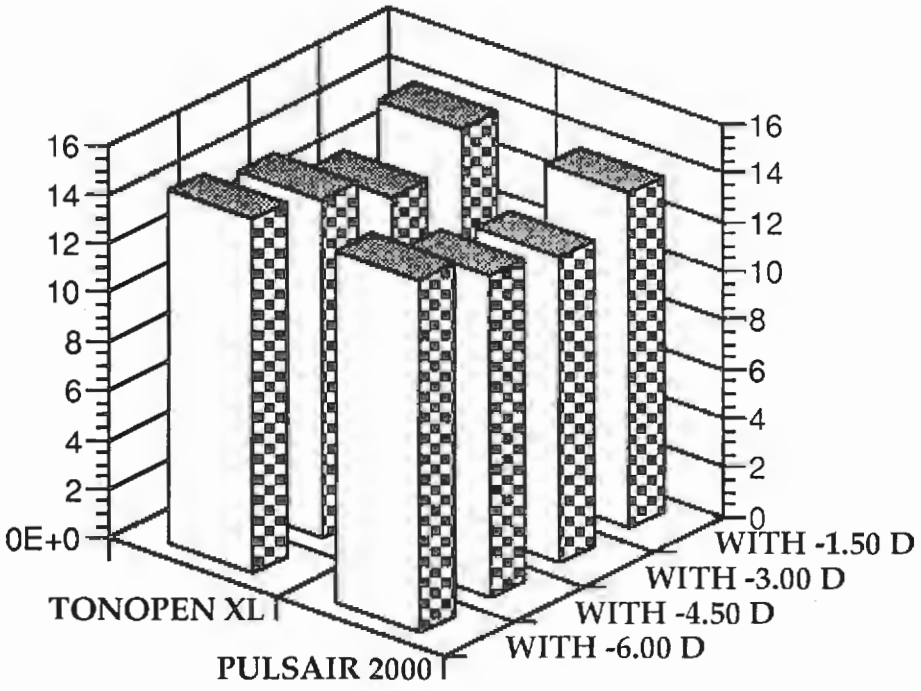
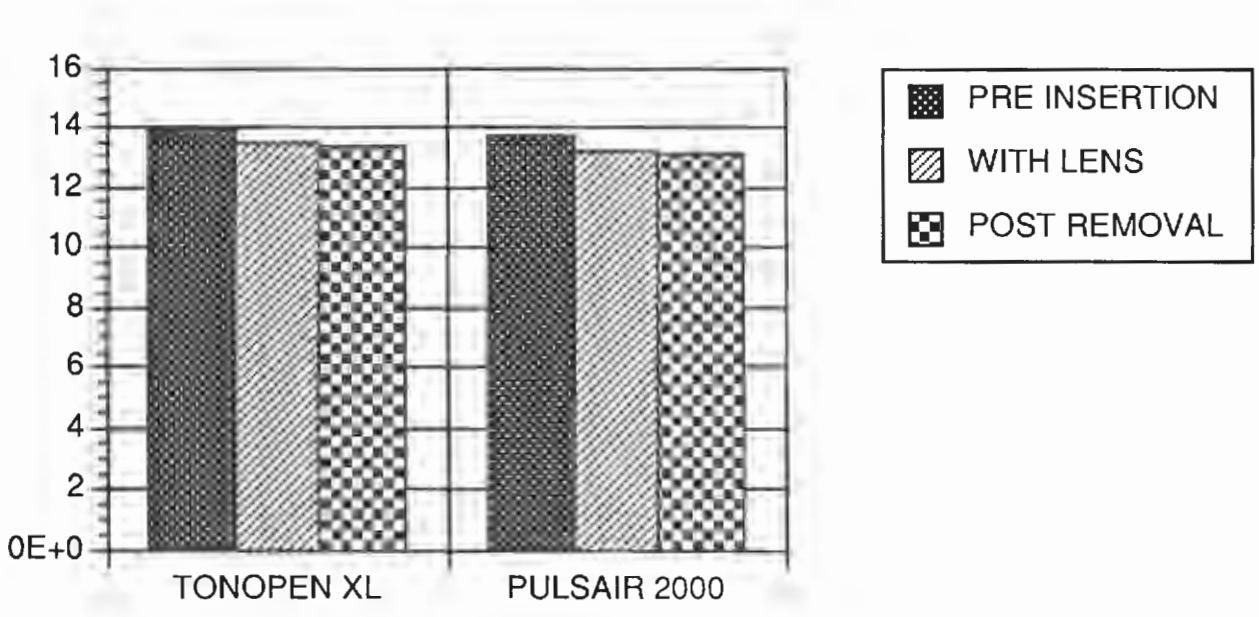


Figure 2 is a graphical representation of the AC incidence table and shows the mean IOP values obtained using Tonopen XL and Pulsair 2000. The overall difference in IOP measurements between the two tonometers (N=40) was within 1mm, across the different experimental conditions. This demonstrates that the IOP was not affected by the method used to deform the cornea.

FIGURE 2

COMPARISON OF IOP MEASUREMENTS BETWEEN TONOPEN XL AND PULSAIR 2000:



DISCUSSION:

One of the two questions addressed in this study was whether IOP measurements performed over minus soft contact lenses, is affected by the refractive power of the lens. It was found that for mid-water content lenses of vifilcon material having a base curve of 8.6 mm, diameter of 14.0 mm and a central thickness of 0.10 mm, there were no significant differences in IOP for any of the refractive powers tested. The second question was whether the accuracy of IOP measurements made over soft contact lenses was affected by the method used to deform the cornea. This study found that the type of tonometer used did not significantly affect the accuracy of IOP measurements.

Accuracy of IOP, as shown in this study, was not affected by minus lenses but other studies show that IOP measured over plus lenses is less reliable. A previous study attributed this to power.[11] This was a manometric study, where the Tonopen was used to measure IOP (ranging from 10 to 60 mm Hg) in a cadaver eye over soft contact lenses of different powers (plus and minus). However, it is difficult to conclude from this study whether the accuracy of IOP was affected by the power of the contact lens, the limitations of the Tonopen, or both. The Tonopen underestimates IOP at higher ranges which could have affected the accuracy both with and without lenses. This was shown in a study,[10] where the IOP of 9 cadaver eyes was set by a manometer at 10 mm Hg increments from 10 to 50 mm Hg. Pressure measurements at each of these settings were taken over four brands of therapeutic contact lenses. It was found that at higher IOP ranges, the Tonopen consistently underestimated manometric pressures, however, the IOPs assessed with lenses were compatible to measurements without lenses.

The apparent disparity between conclusions in the different studies seems to be because of the varied types of lenses used (power, central thickness, material); choice of subjects (live vs eye bank eyes); and the range of IOPs studied (normal vs high). A careful

review of the different studies shows that the two factors which can affect IOP measurements are the type of lens and the accuracy of the tonometer.

CONCLUSIONS:

This study concludes that the measurement of IOP over minus lenses with the Tonopen XL the Pulsair 2000 tonometers are reliable and that standard minus power soft contact lenses do not affect the readings. Removal of contact lenses to measure IOP would be advocated if the patient is wearing a plus lens or if the IOP measurement is greater than 21 mm Hg. Taking multiple IOP readings and using the average would be recommended, to overcome any effect of variability. Until more accurate correlations are found between these tonometers and Goldmann at hypertensive and glaucomatous levels, follow up with Goldmann tonometer is recommended, when patients with elevated pressures are encountered.

FOOTNOTES:

a- Personal communication with Ciba Vision representative.

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